IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

BRUCE N. SAFFRAN, M.D., PH.D., Plaintiff,	§	
v.	§	CIVIL ACTION NO. 2:07-CV-451 (TJW)
JOHNSON & JOHNSON and CORDIS CORPORATION, Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court are various *Daubert* Motions filed by both parties. (Dkt. Nos. 182, 183, 193, 194, and 195.) The Court has carefully considered the parties' submissions, the record, and the applicable law. The following Memorandum Opinion and Order sets forth the Court's rulings.

I. BACKGROUND

Plaintiff Bruce N. Saffran, M.D., Ph.D. has brought the abovestyled patent infringement lawsuit against Defendants Johnson & Johnson ("J&J") and Cordis Corporation ("Cordis") (collectively "Defendants"). Saffran asserts U.S. Patent No. 5,653,760 (the '760 Patent) in this lawsuit. Defendants' accused products are the Cypher drug-eluting stents (including the Cypher Select and Cypher Select Plus). (Dkt. No. 234.) Jury selection is set for Friday, January 21, 2011. This Memorandum Opinion and Order pertains to the parties' various *Daubert* Motions.

II. LEGAL STANDARD

The trial court acts as a "gatekeeper" to exclude expert testimony that does not meet the relevancy and reliability threshold requirements. In this role, the trial court determines the admissibility of expert testimony based on Federal Rule of Evidence 702 and *Daubert v. Merrell*

Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Accordingly, opinion testimony is not admissible unless: (1) the witness is qualified "as an expert by knowledge, skill, experience, training, or education," Fed. R. Evid. 702; (2) the witness' reasoning or methodology underlying the opinion testimony is scientifically reliable, *Daubert*, 509 U.S. at 592-93; and (3) the testimony is relevant—that is, it must assist the trier of fact to understand the evidence or to determine a fact at issue. Fed. R. Evid. 702; *Daubert*, 509 U.S. at 591.

To satisfy the reliability prong of *Daubert*, an expert's opinion testimony must be based upon "sufficient facts or data" and must be "the product of reliable principles and methods" that are "reliably" applied "to the facts of the case." Fed. R. Evid. 702 & advisory committee note. When evaluating the reliability of the proffered testimony of an expert, "Rule 702 demands that expert testimony relate to scientific, technical or other specialized knowledge, which does not include unsubstantiated speculation and subjective beliefs." *Diviero v. Uniroyal Goodrich Tire Co.*, 114 F.3d 851, 853 (9th Cir. 1997) (citing *Daubert*, 509 U.S. at 590). "The reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion." *Knight v. Kirby Inland Marine, Inc.*, 482 F.3d 347, 355 (5th Cir. 2007) (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999)). "But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). However, "[w]hen the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010). That is, a trial court is not permitted under *Daubert* to

"transform a *Daubert* hearing into a trial on the merits." *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 250 (5th Cir. 2002).

III. DISCUSSION

A. Defendants' *Daubert* Motion No. 1 (Dkt. No. 182)

Defendants' motion that Dr. Freeman's untested speculation about Cordis's experiments be inadmissible is DENIED as moot in accordance with Docket Number 226. Defendants' request that Dr. Shebuski's opinions regarding why early attempts by Cordis to create a drug-eluting stent failed is DENIED for the following reasons.

In the second part of Defendants' *Daubert* Motion No. 1 (Dkt. No. 182), Defendants seek to exclude opinion by Dr. Shebuski, Plaintiff's proposed expert on the pharmacokinetics of the Cypher stent, regarding why early attempts by Cordis and other stent manufacturers failed to create a drug-eluting stent. Defendants state that Dr. Shebuski opines in a "wholly conclusory" manner that pre-Cypher attempts to create a drug eluting stent failed because Cordis and other companies did not use the technology covered by the patent-in-suit, the '760 patent. (Dkt. No. 182, at 7.) Defendants allege that Dr. Shebuski has no support for these "bare assertions." (*Id.*)

The Court disagrees with Defendants' assessment of Dr. Shebuski's opinion, as Dr. Shebuski is not wholly conclusory in his opinion. Dr. Shebuski provides at least two pages of analysis in his expert report regarding why, in his opinion, Cordis and others had failed attempts to create a drug-eluting stent. (*See* Expert Report of Ronald J. Shebuski, Ph.D., Dkt. No. 182-18, at 9-10.) For example, in one portion of his report, Dr. Shebuski states:

> In my view, these attempts failed because Cordis did not appreciate the importance of preferentially releasing the drug directionally toward the arterial wall via chemical bonds and linkages. For example, scientists initially attempted to deliver heparin from stents to treat endothelial injuries. COREV0583655-56. Instead, heparin washed away in the bloodstream. *Id.*; COR0145001-04.

(*Id.* at ¶ 24.) Although, as Defendants state in their brief, Dr. Shebuski may not have always mentioned the particular stent being used, dosing of the drug on the stent, or means of bonding the drug to the stent for each example discussed in his report (Dkt. No. 182, at 8), these failures are proper subjects for cross-examination. They do not affect the admissibility of the opinion. Thus, Defendants' motion is DENIED.

B. Defendants' *Daubert* Motion No. 2 (Dkt. No. 183)

Defendants' *Daubert* Motion No. 2 is DENIED for the following reasons. Defendants seek to preclude Plaintiff's expert, Dr. Freeman, from testifying that the accused Cypher stent meets the directional release limitations of the asserted claims based on the effect that human blood and tissue have on Cypher. (Dkt. No. 183, at 2.) Defendants state that Dr. Freeman is not an expert regarding the contents and composition of blood and tissue, as Dr. Freeman is a chemical engineer and not a biologist. (*Id.*) Dr. Freeman himself has even admitted in a deposition that he is "not an expert on the detailed contents and composition of tissue and blood." (*Id.* at 5.) Thus, Defendants argue that Dr. Freeman is not qualified to testify as an expert on these subjects and should not be permitted to testify concerning his beliefs regarding how the properties of blood and tissue affect the release of drug from the Cypher stent.

The Court disagrees with Defendants that Dr. Freeman is not qualified. Dr. Freeman is not providing an expert opinion regarding the contents and composition of tissue and blood. Instead, Dr. Freeman is providing an opinion regarding the presence and characteristics of chemical bonds and the transport of molecules in a chemical environment (i.e., inside the body). Dr. Freeman's background in chemical engineering is sufficient to render such an opinion. Although Dr. Freeman uses information regarding the contents and composition of blood and tissue in forming his opinion, Dr. Freeman relies on scientific literature and/or Defendants' own

documents to form his opinion. (*See* Dkt. No. 231, at 6-7 (listing several of Defendants' documents that Dr. Freeman relies on).) An expert is allowed to rely on such information in forming his or her opinion. *See United States v. Avants*, 367 F.3d 433, 447 (5th Cir. 2004) ("Expert witnesses are permitted, of course, to draw on a wide range of sources in forming their opinions."). Thus, Dr. Freeman relies on information from other sources to provide a starting point for his analysis (i.e., characteristics of blood and tissue), and then Dr. Freeman uses his expertise in the field of chemical engineering, which is not disputed, to form an opinion on the interaction and transport of the alleged chemical bonds and/or linkages regarding the Cypher stent and its use. Dr. Freeman is not unqualified to give such an opinion and Defendants' Motion is therefore DENIED.

C. Plaintiff's Motion to Exclude Portions of the Defendants' Expert Reports that are Based Upon Claim Construction Other Than the Court's Claim Constructions (Dkt. No. 193)

The Court GRANTS-in-part and DENIES-in-part this Motion. This particular motion has three different parts which are discussed below.

First, Plaintiff seeks to preclude Defendants' experts from offering testimony or evidence that the mere fact that Cypher contains more than one layer precludes a finding of infringement. This request for relief is GRANTED. The Court has construed "layer" to mean "a single layer" in its Claim Construction Order. (Claim Construction Order, Dkt. No. 111, at 16.) This means, for there to be infringement of a '760 Patent claim, all of the limitations requiring a "layer" in the claim must be met with a "single layer" of the accused device. But as the Court stated in its Claim Construction Order, the claims use the "comprising" transitional phrase and Plaintiff will be able to take advantage of this open ended term that is well known in patent law. (*Id.* at 19-20.) The mere fact that the accused device has more than a single layer does not preclude

infringement so long as all of the limitations from a '760 Patent claim requiring a "layer" are satisfied by a "single layer" in the accused device. Therefore, Defendants' experts may not opine that *the mere fact* that there are two layers on the Cypher stent precludes infringement. Nothing in this Order precludes, however, Defendants from arguing or providing expert testimony that all of the "layer" limitations of the '760 Patent cannot be satisfied with a single layer of the Cypher stent.

Second, Plaintiff seeks to preclude Defendants' experts from reintroducing rejected claim construction arguments regarding a sheet. This request for relief is GRANTED. The Court declined to construe the term "device," as Defendants' requested, to be "a single sheet of material" in its Claim Construction Order. (Dkt. No. 111, at 9-10.) As already discussed at the pre-trial hearing, Defendants may not refer to the invention as requiring a "sheet" because it is merely a preferred embodiment. The invention is described by the claims as construed by this Court. But Defendants maintain that they do not plan to introduce evidence or argue that the '760 Patent's device must be a sheet or that Cypher does not infringe because it has only a sheet. (Dkt. No. 227, at 5.) Nothing in this Order precludes, however, the defendants from cross examining the inventor with references to the preferred embodiment, so long as the questions are appropriately couched as such. Moreover, nothing in this Order should be read to preclude the defendants from arguing that prior art references that include a sheet necessarily satisfy various limitations as construed by the Court.

Third, Plaintiff seeks to preclude Defendants from arguing that the "capable of being shaped in three dimensions by manipulation by human hands" limitation in the asserted claims requires the layer to be capable of being shaped independent of it being applied to the stent or other structure. This request for relief is DENIED. As discussed above, however, if the Court

finds the Defendants are inappropriately characterizing the law or this Court's Claim Construction Order, the Court will remedy that issue at the appropriate time or in its final instructions.

D. Plaintiff's Motion to Preclude Defendants' Expert, Dr. Atwood, from Offering Testimony Regarding Anticipation and Dr. Saffran's Alleged Misrepresentations to the PTO (Dkt. No. 194)

The Court GRANTS-in-part and CARRIES the remainder of this Motion. The first part of Plaintiff's motion, that Dr. Atwood's anticipation opinion is based upon erroneous legal conclusions, is GRANTED for the reasons set forth below. The second part, which argues that Dr. Atwood cannot testify regarding Dr. Saffran's alleged misrepresentations to the PTO, is CARRIED pursuant to the parties' agreement in Docket Number 262. As the parties state, this issue is only germane to the bench trial.

Dr. Atwood is one of Defendants' experts and he provides an opinion on anticipation of the '760 Patent. Dr. Atwood opines that the '760 Patent is anticipated by Schwartz, U.S. Patent Number 5,282,823 ("Schwartz" Patent). One of the limitations of the '760 patent is the means-plus-function limitation "material release means," which this Court has construed to have a structure of "chemical bonds and linkages." (Dkt. No. 111, at 23-24.) Dr. Atwood opines that Schwartz teaches chemical bonds and linkages in two ways: (1) variations of polymer-to-polymer linkages; and (2) teachings of Wolff, which Defendants' argue is incorporated by reference in Schwartz, of "different ways of attaching the drug to a polymer." Each is discussed below.

1. The Polymer-to-Polymer Linkages Taught by Schwartz

a. Background and Argument by the Parties

Dr. Atwood opines that the Schwartz patent teaches chemical bonds and linkages in its disclosure of two different polymer-to-polymer linkages. Dr. Atwood states that one type of chemical bonds and linkage that Schwartz discloses is "[t]herapeutic substances (treating materials) that can be placed 'on the surface of the film or incorporated into the film as it is made.'" (Dr. Atwood Expert Report, attached as Ex. A to Dkt. No. 194, at 13 (quoting Schwartz at 7:14-17).) Dr. Atwood's report states that one type of material that can make the polymeric film discussed in Schwartz is polylactic acid. (*Id.*) Polylactic acid is a biodegradable polymer that, in the presence of water, will have its chemical bonds and linkages broken by hydrolysis. (*Id.*) Dr. Atwood states:

> As the chemical bonds and linkages of the polylactic acid polymer are broken by water, the polymer degrades, exposing more of the polymer. That polymer degradation further exposes the drug on the surface of the flexible film so that it is no longer held in place by the polymer and is free to enter the blood vessel, which it does. Because, for example, when the drug is placed only on the surface of the polylactic acid layer adjacent to the damaged tissue, once the polymer is hydrolyzed, the drug can only go into the blood vessel.

(*Id.* at 14.) Another type of polymer-to-polymer linkage discussed by Dr. Atwood is the "microcapsules" disclosed by Schwartz. (*Id.* at 14.) Schwartz discloses "microcapsules [that] can be used to carry the therapeutic substances either in or on the film and to provide a timed-release of the substance to the blood or to the blood vessel or both. Schwartz Patent, 7:17-20. One example Schwartz gives of its "microcapsules" is U.S. Patent No. 4,897,268 (the '268 Patent), which Schwartz incorporates by reference along with several other patents. *See id.* at 7:23-25. The '268 Patent describes a biodegradable microcapsule delivery system where ingredients are encapsulated in a biodegradable copolymer and then the ingredients may be

released over a period of time as the copolymer excipients break down at various rates. '268 Patent, Abstract. As Dr. Atwood describes, "[t]hose microcapsules release drugs as the chemical bonds or linkages of the polymer making up the microcapsule are broken." (Dkt. No. 192, Ex. A, at 14.)

The Court observes that in both teachings that Dr. Atwood describes above, it is the polymer-to-polymer bonds that constitute the chemical bonds and linkages, which is the structure of the "material release means" limitation of the '760 Patent. Neither teaching in the Schwartz Patent describes releasing a drug by means of breaking a chemical bond or linkage *with the drug*. Instead, in the polylactic acid teaching, the drug is released as the polymer-to-polymer bonds of the polylactic acid break down and expose the drug on the surface of the film. (Dkt. No. 194, at 14.) Further, in the microcapsule teaching, the polymer-to-polymer bonds of the microcapsule are broken, which then releases the drug. Plaintiff, as a result, argues that the focus of the "chemical bonds and linkages" structure is on drug-to-polymer bonds in the '760 Patent. This was not an argument brought before the Court in the *Marking* briefing or hearing, thus the Court will treat this as a request to clarify its Claim Construction Order insofar as its construction of the "material release means."

b. Clarification of the Court's Construction of "Material Release Means"

As the Court stated in its Claim Construction Order:

> The Court concludes that the phrase "means for release of at least one treating material in a directional [or unidirectional] manner" is governed by 35 U.S.C. §112 ¶ 6. The Court also concludes that the function of this means-plus-function claim is "to release a drug preferentially toward the damaged tissue." The Court concludes the corresponding structure is "chemical bonds and linkages."

(Dkt. No. 111, at 23-24.) In view of the present motion, the Court clarifies that the structure of "chemical bonds and linkages" is referring to the chemical bond or linkage between the drug and the device.

The intrinsic record, namely the specification, strongly supports this clarification by the Court. The Federal Circuit law on identifying the structure of a means-plus-function is clear. The "structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." *Medical Instrumentation and Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003), *citing B. Braun v. Abbott Labs*, 124 F.3d 1419, 1424 (Fed. Cir. 1997). The patentee must clearly link or associate structure with the claimed function as part of the quid pro quo for allowing the patentee to express the claim in terms of function pursuant to § 112, ¶ 6. *See id.* at 1211; *see also Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1377 (Fed. Cir. 2001). As noted in the Court's Claim Construction Order, the structure "clearly linked" by the patentee is "chemical bonds and linkages." But, more specifically, the specification "clearly links" the chemical bonds and linkages between the drug (or medicine) and the device. For example, the specification states that "[r]elease rates can be adjusted simply by varying the linkage *between the medicine and the device*." '760 Patent, 14:64-65 (emphasis added). The specification also describes how the "medicine" is attached using a hydrolyzable bond. '760 Patent, 14:58-61 ("I have found that I can achieve prolonged duration and much more stable rate of efflux from the device when medicine is attached using a hydrolyzable bond."). Finally, as the Court pointed out in its Claim Construction Order (Dkt. No. 111, at 27), Figure 3a clearly shows the "treating material" (reference numeral 12) affixed by a "chemical bond" (reference

numeral 24) to the "sheet" embodiment (reference numeral 1) of the device. *See* '760 Patent, Figure 3a; 10:21-55 (listing the reference numerals).

As a result of this clarification, Plaintiff's request to strike the portion of Dr. Atwood's opinion and report referring to the polymer-to-polymer teachings of the Schwartz Patent is GRANTED. As discussed above, neither teaching in the Schwartz Patent, which is discussed by Dr. Atwood, describes a structure of a chemical bond or linkage between the drug and the device—only the polymer-to-polymer bonds and linkages. Thus, to the extent Schwartz teaches a "material release means" with a structure of polymer-to-polymer bonds or linkages, it does not teach the "material release means" limitation of the '760 Patent.

2. Dr. Atwood's Conclusion that Schwartz Incorporates by Reference Wolff's Teachings of Various Methods to Attach a Drug to a Polymer.

Plaintiff argues that Dr. Atwood should be precluded from opining that Schwartz incorporated Wolff's teaching of "different ways of attaching the drug to a polymer," because the incorporation is wrong as a matter of law. The Court agrees with Plaintiff and GRANTS Plaintiff's motion to preclude Dr. Atwood from giving such an opinion.

"Whether material is incorporated by reference into a host document is a question of law." *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009). "To incorporate a matter by reference, a host document must contain language 'clearly identifying the subject matter which is incorporated and where it is to be found'; a mere *reference* to another application, or patent, or publication is not an *incorporation* of anything therein . . . ." *Id.* (citing *In re De Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973)) (emphasis in original). In other words, "the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1283 (Fed. Cir. 2000).

The particular reference that Defendants' argue is incorporated by Schwartz is International Patent Application WO 91/12779 "Intraluminal Drug Eluting Prosthesis" (the "Wolff" reference). Plaintiff agrees that Schwartz incorporates Wolff's "therapeutic substances" teaching at different portions of the Schwartz Patent. *See* Schwartz Patent, 2:59-65, 3:65-4:3, and 7:1-7. Defendants, however, argue that in addition to the "therapeutic substances," Schwartz also incorporates Wolff's disclosure of methods of incorporation of a drug for use in or on Schwartz's polymer film. (Dkt. No. 233, at 7.) Plaintiffs, of course, argue that Schwartz incorporates only Wolff's "therapeutic substances." The relevant language of the Schwartz Patent reads:

> Since the stent of the present invention has a polymeric surface in contact with the body lumen, the stent [can/may] also incorporate therapeutic substances in or on the polymeric film such as those disclosed in [Wolff], which is incorporated herein by reference.

Schwartz Patent, 2:59-65 & 3:65-4:3 (the only difference between 2:59-65 and 3:65-4:3 is the "can" and "may" that are noted in brackets in the quoted text above). The Court agrees with Plaintiff that Schwartz only incorporates Wolff's "therapeutic substances." In accordance with the Federal Circuit case law, the "therapeutic substances" of Wolff are the only material that is identified with "detailed particularity" in the Schwartz Patent. The Schwartz Patent does not mention any other portion of Wolff besides its "therapeutic substances." The Court disagrees with Defendants' argument that Schwartz meant to incorporate the method Wolff places the therapeutic substances "in or on" the polymers in Wolff. The grammar of Schwartz at 2:59-65 and 3:65-4:3, quoted above, uses the modifier "those," which refers to the plural noun "therapeutic substances." That the "therapeutic substances" are placed "in or on the polymeric film" makes no difference. It would be a stretch to hold that the above-quoted language from

Schwartz is identifying with "detailed particularity" Wolff's *method* of binding drugs to polymers.

Thus, the Court GRANTS Plaintiff's motion to preclude Dr. Atwood from opining that Schwartz incorporated Wolff's teaching of "different ways of attaching the drug to a polymer."

E. Plaintiff's Motion to Preclude Defendants' Damages Expert, Christopher Bakewell, from Referencing, or Relying On, the *Saffran v. Boston Scientific Corp.* Settlement Agreement (Dkt. No. 195)

Pursuant to the parties' agreement regarding the parties' motions *in limine* on the same subject and the parties' discussion with the Court at the pre-trial hearing, the parties have agreed that this Motion should be DENIED as moot.

IT IS SO ORDERED.

SIGNED this 20th day of January, 2011.

T. John Ward

T. JOHN WARD
UNITED STATES DISTRICT JUDGE